

### **Remarks**

Claims 1-20 are pending. Claims 1-10 have been withdrawn from consideration. Thus, claims 11-20 remain under consideration.

### **§ 103 Rejections**

Claims 11-20, of which claim 11 is the only independent claim, stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Pat. No. 5,750,136 ("Scholz") in view of U.S. Pat. No. 5,527,610 ("Urry").

The Office Action states that Scholz discloses a bioadhesive composition that adheres suitably to a mucosal surface and is capable of delivering drugs in sustained fashion. The bioadhesive composition of Scholz comprises (1) a particulate polymeric resin, (2) a hydrophobic elastomeric component, and (3) a drug. The Office Action acknowledges that Scholz does not disclose the elastomeric polymer to be crosslinked.

Urry is said to disclose a bioelastomer comprising tetrapeptide and/or pentapeptide monomeric units. The bioelastomer can be crosslinked or uncrosslinked, and increased amounts of cross-linking are appropriate for increasing demands of rigidity.

The Office Actions argues that, absent unexpected results, it would have been obvious to one of ordinary skill in the art to modify the elastomeric polymer taught by Scholz by crosslinking the polymer to provide strength and rigidity as taught by Urry. Applicants respectfully traverse the rejection.

The rejection of claims 11-20 under 35 U.S.C. § 103(a) fails to set forth a *prima facie* case of obviousness. M.P.E.P. § 706.02(j) states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings;
- (2) there must be a reasonable expectation of success;
- (3) the prior art reference(s) must teach or suggest all of the claim limitations.

Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure.

Applicants assert that a *prima facie* case of obviousness has not been established for all of the reasons set forth in the previous response. In addition to the reasons already made of record, Applicants assert that the combination of Urry and Scholz is improper because one of ordinary skill in the art at the time the invention was made would have had no motivation to combine the references as suggested in the Office Action.

The Office Action advances the argument that the teaching of Urry would have motivated one of skill in the art to combine the teachings of Urry and Scholz because Urry teaches that “increasing amounts of cross-linking are appropriate for increasing demands of rigidity.” This observation in Urry is relevant to a § 103 rejection of the present claims *only if* Scholz taught or suggested that increased rigidity of the bioelastic polymer is desirable.

The Federal Circuit has been quite clear: “...particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.” *In re Lee*, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002) (citing *In re Rouffet*, 47 U.S.P.Q.1453, 1459 (Fed. Cir. 1998)). In the absence of Applicants’ disclosure, there is no teaching or suggestion in the cited references that would have led the skilled artisan to apply the teaching of Urry - “increasing amounts of cross-linking are appropriate for increasing demands of rigidity.” – to the teachings of Scholz. For example, there is no teaching in either reference that the bioadhesive compounds of Scholz could be improved by adjusting the degree of cross-linking in the elastomeric polymer. Therefore, there is no teaching or suggestion leading the skilled artisan to combine the cited references as suggested in the Office Action. Thus, the combination of Scholz and Urry is improper and the rejection of claim 11 based on the combination of Scholz and Urry should be withdrawn.

Furthermore, Applicants respectfully submit that the skilled artisan would have lacked motivation to combine the references as suggested in the Office Action because the teaching of Urry, as characterized in the Office Action, is incomplete. While Urry does, in fact, teach bioelastic polymers, the polymers are intended to *prevent* adhesion of biological materials to a surface. The biopolymers of Urry can be used “for substantially preventing cellular adhesion by forming a protective layer between a first surface and a second surface using the present bioelastomers.” The surfaces include *cells* and *tissue* (column 9, lines 56-62). Therefore, it is unclear why one of ordinary skill in the art of bioadhesives for use in a mucosal drug delivery device (seeking to *promote* adhesion between the device and a mucosal surface of a subject)

would have been motivated to consider a reference that teaches bioelastic polymers designed to *prevent* adhesion between biological materials, including surfaces of cells and/or tissues.

Because one of skill in the art would not have been motivated to combine the cited references as suggested in the Office Action, the combination of Scholz and Urry is improper and the rejection of claim 11 based on the combination of Scholz and Urry should be withdrawn.

Even if, for the sake of argument, the combination of Scholz and Urry establishes a *prima facie* case of obviousness, Applicants submit that the present disclosure provides precisely the unexpected result the renders the subject matter of claim 11 patentable over the combination of Scholz and Urry. Applicants submit that bioadhesive compositions of the present invention provide unexpected improved bioadhesion compared to compositions disclosed in Scholz. Furthermore, nothing in Scholz or Urry teaches or suggests improving bioadhesion through manipulating the extent of crosslinking in the elastomeric polymer.

Example 1 (Table 1 and Figures 1-3) illustrate the improved bioadhesive properties of compositions according to the present invention - those containing Carbopol 971P as the crosslinked elastomeric polymer – and similar compositions including a crosslinked elastomeric polymer disclosed in Scholz, Carbopol 934P (See Scholz, column 3, lines 43-48). In each case, the bioadhesive composition of the present invention (Formulations E, H, and J) provide superior bioadhesion compared to the compositions prepared using the crosslinked elastomeric polymer disclosed in Scholz (Formulations A, G, and I).

Figure 1 shows that Formulation E (a) provided a greater adhesion score at each time point than Formulation A, and (b) maintained an adhesion score greater than or equal to 1 for twenty-four hours. Formulation A maintained an adhesion score of greater than or equal to 1 for only two hours.

Figure 2 shows that Formulation H maintained an adhesion score of greater than or equal to 1 for eight hours compared to only four hours for Formulation G. Formulation H also provided a greater adhesion score than Formulation G for each time point beginning at three hours.

Figure 3 shows that Formulation J provided greater adhesion or equal adhesion than Formulation I at each time point. Also, Formulation J provided an adhesion score greater than or equal to 1 for 24 hours. Formulation I provided an adhesion score greater than or equal to 1 for only eight hours.

Thus, whether one desires increased adhesion strength or longer lasting adhesion, compositions of the present invention – those including a cross-linked elastomeric polymer being 30-80% crosslinked – provide superior adhesion properties compared to bioadhesive compositions including cross-linked elastomeric polymers disclosed in Scholz.

The rejection of claim 11 under 35 USC § 103(a) as being unpatentable over Scholz in view of Urry is improper and should be withdrawn.

Each of claims 12-20 depends, directly or indirectly, from claim 11 and is therefore patentable for at least all of the reasons set forth above regarding the patentability of claim 11.

In summary, the rejection of claims 11-20 under 35 USC § 103(a) as being unpatentable over Scholz in view of Urry is improper and should be withdrawn.

### **Conclusion**

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application and allowance of claims 11-20 is requested.

Respectfully submitted,

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